Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658178	08/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorios Ramirez, Llc	8133 Calle Concordia Suite 101, Ponce, PR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Microscan microorganisms identification(ID) and antimicrobial susceptibility tests quality system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation and interview testing personal #2 on August 21, 2018 at 9:25 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology from January 2, 2017 to August 20, 2018. Refer to D 5471 (The laboratory did not check each batch, lot number and shipment of reagents of Microscan microorganisms identification system for positive and negative reactivity of each substrate included in this identification system from January 2, 2017 to August 20, 2018). Refer to D 5507 (The laboratory failed check with appropriate control organism(s) each batch, lot number, shipment of reagents and each day of testing the Microscan antimicrobial susceptibility tests from July 31, 2017 to August 20, 2018). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on manufacturer's instructions, Antinuclear Antibody (ANA) IgG by Immunofluorescence quality control records review in year 2018 and laboratory technical supervisor interview at 1:00 PM on August 21, 2018, it was determined that the laboratory failed to ensure compliance with analytic system requirements for general immunology. Refer to D5403 (The laboratory did not have the procedure manual for Antinuclear Antibody (ANA) IgG test by immunofluorescence kit.), D5405 (The laboratory did not follow the manufacturer's instructions when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit with 1:40 screening dilution) and D5411 (The laboratory did not follow the manufacturer's instructions for temperature incubation when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit with temperature range). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on written policies for sperm cell analysis and count specimens, sperm cell testing records(years 2017 to 2018) and testing personnel # 2 interview on August 21, 2018 at 11:20 AM, it was determined that the laboratory failed to have and follow written procedures for the acceptability and rejection of the sperm cell analysis that was collected out side the laboratory from January 4, 2017 to August 20, 2018. The findings include: 1. The written procedures for the collection of the sperm cell analysis and count specimens did not include specific instructions of rejections for the sperm cell analysis that were not taken in the laboratory. 2. The testing personnel confirmed on August 21, 2018 at 11:20 AM, that the laboratory did not have specific instructions of rejections for the sperm cell analysis that were not taken in the laboratory. She stated that the laboratory did not document the receipt time in to the laboratory. She stated, that she does not know how many sperm cell analysis were taken out side the laboratory from January 4, 2017 to August 20, 2018. 3. On August 21, 2018 at 11:20 AM, the sperm cell testing records showed that the laboratory processed 168 from January 4, 2017 to August 20, 2018. 35 out of 168 sperm cell specimens did not include the time of collection and 168 out of 168 did not include date and receipt time.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on lack of the Antinuclear Antibody (Ana IgG) procedure manual, Ana IgG testing records, Lumen fluorescence microscopy records review and laboratory technical supervisor interview on August 21, 2018 at 1:00 PM, it was determined that the laboratory failed to have a written procedures for Antinuclear Antibody (ANA) IgG test processed by immunofluorescence kit since from January 30, 2018 to August 10, 2018. The findings include: 1.The laboratory performed Antinuclear Antibody (ANA) IgG test by immunofluorescence kit and used the uses a LW Scientific, model Mi5 Lumen fluorescence microscopy. 2.The laboratory did not have a written procedures for Antinuclear Antibody (ANA) IgG test processed by immunofluorescence kit since Janaury 30, 2018 with the following requirements: Requirements for patient preparation, specimen collection, storage, preservation, transportation, processing and referral criteria for specimen acceptability and rejection; Normal values; Limitations in the test methodology, including interfering substances; Pertinent literature references; Criteria to determine acceptable control results and Preparation of controls used in the test. 3. The technical supervisor stated on August 21, 2018 at 1:00 PM, that the laboratory has the procedures manual but it was not available. 4. The laboratory processed and reported 162 out of 162 patients speciemens for ANA IgG tests from from January 30, 2018 to August 10, 2018.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: A. Based on Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), laboratory information system (LIS) and interview with the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the laboratory failed to follow manufacturer instructions for the processing and reporting of 5 out of 5 pediatric population serum specimens from January 2, 2017 to August 20, 2018. The findings include: 1. Immuno Card H. Pylori manufacturer indicated as limitations of the Immuno Card H. Pylori procedure, that this method has

	not being tested in pediatric populations. Therefore, no performance characteristics had being established for this group. 2. The H. Pylori testing records showed that the laboratory used the Immuno Card H. Pylori tests from January 2, 2017 to August 20, 2018. 3. On August 21, 2018 at 12:40 PM, the LIS showed that the laboratory processed and reported 5 out of 5 pediatric population serum specimens by the Immuno Card H. Pylori test from January 2, 2017 to August 20, 2018: Report Patients Patients Date ID Age March 25, 2017 #3250034 14 years October 26, 2017 #10250006 13 years February 8, 2018 #280022 11 years May 5, 2018 #05050056 15 years June 26, 2018 #06260049 9 years 4. The technical supervisor confirmed on August 21, 2018 at 12:40 PM, that the laboratory processed and reported those pediatric samples. He also stated, that he did not know about this manufacturer's limitation. 30930 B. Based on VIRGO manufacturer's instructions, Antinuclear Antibody (ANA) IgG by Immunofluorescence testing records review(year 2018) and laboratory technical supervisor interview on August 21, 2018 at 1:00 PM , it was determined that the laboratory failed to follow the manufacturer's instructions for processing 69 out of 69 patients specimens ANA IgG test by immunofluorescence kit from January 30, 2018 to August 10, 2018. The findings include: 1.The laboratory uses VIRGO Antinuclear Antibody immune fluorescence test kit for the detection of ANA IgG qualitative and quantitative tests from January 30, 2018 to August 10, 2018. 2.The manufacturer's instructions establish in the test procedure (step 3) that the laboratory dilute the samples with the PBS to the 1:40 screening dilution or prepare serial two-fold dilutions for quantitative determination, beginning with the 1:40 screening dilution. 3.On August 21, 2018 at 1:00 PM, the ANA IgG testing records showed that the laboratory did not perform the 1:40 screening dilution when it processed and reported 69 out of 69 patient's samples with negative results. 4.The laboratory technical supervisor confirmed on August 21, 2018, that the ANA IgG testing records did not include the 1:40 screening dilution in the 69 patient's samples reported with negative results. He stated that he does not know how this tests were performed. He also stated that the testing personnel #4 performed this test and she was in vacation, but indicated that the testing personnel #4 said that she performed serial dilutions until 1:1280 in every patients specimens but only reported the patients specimens with positive reactions. 5. The laboratory did not have available the ANA IgG procedures manual. Refer to D 5403.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on VIRGO manufacturer's instructions, Antinuclear Antibody (ANA) IgG by Immunofluorescence quality control records review (2018) and laboratory technical supervisor interview on August 21, 2018 at 1:00 PM, it was determined that the laboratory failed to follow the manufacturer's instructions for temperature of incubation when patients specimens were performed for ANA IgG test by immunofluorescence kit from January 30, 2018 to August 14, 2018. The findings include: 1. The laboratory uses VIRGO Antinuclear Antibody immune fluorescence test kit for the detection of ANA (Antinuclear Antibody) IgG from January 30, 2018 to August 14, 2018. 2. The manufacturer's instructions establishes in the test

	procedure (step 6 and Step 11) that the slides with diluted samples or controls are incubated in a humidified chamber at 23 2 C for 30 minutes. 3. On August 21, 2018 at 1:00 PM, the ANA test temperature record showed 49 out of 49 days that the laboratory processed and reported patients specimens for ANA tests with temperatures out of the required range, from January 30, 2018 to August 14, 2018: Date Temp. 1/30 /18 19.1 2/2/18 19.0 2/6/18 18.5 2/9/18 17.0 2/13/18 17.0 2/16/18 18.0 2/20/18 18.0 2 /23/18 18.0 2/27/18 17.0 3/2/18 16.0 3/6/18 18.0 3/11/18 No records 3/13/18 16.0 3/16 /18 18.0 3/20/18 18.0 3/23/18 18.0 4/3/18 18.0 4/6/18 18.0 4/13/18 19.0 4/16/18 18.0 4 /20/18 18.0 4/27/18 19.0 5/1/18 18.0 5/4/18 18.0 5/8/18 19.0 5/11/18 19.0 5/15/18 19.0 5/18/18 19.0 5/22/18 18.0 5/25/18 21.0 5/29/18 21.0 6/1/18 21.0 6/5/18 21.0 6/8 /18 20.0 6/14/18 21.0 6/22/18 20.0 6/29/18 19.0 7/3/18 21.4 7/6/18 22.2 7/10/18 20.8 7 /13/18 21.1 7/17/18 21.4 7/20/18 21.4 7/24/18 21.0 7/27/18 21.1 8/3/18 21.6 8/7/18 21.9 8/10/18 21.3 8/14/18 21.5 4.The laboratory processed and reported one hundred sixty two (162) patient's samples for Antinuclear Antibody (ANA) IgG by fluorescence kit from January 30, 2018 to August 14, 2018. 5.The laboratory technical supervisor on August 21, 2018 confirmed that the laboratory processed and reported 162 ANA IgG patient's samples tests and did not follow that manufacturer's instructions for temperatures incubation those days.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Microscan identification(ID) system quality control records (from August 24, 2016 to August, 21 2018) review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation and interview with the testing personnel #2 on August 21, 2018 at 9:25 AM, it was determined that the laboratory failed check each batch, lot number and shipment of reagents of Microscan ID system for positive and negative reactivity of each substrate included in this identification system from January 2, 2017 to August 20, 2018. The findings include: 1. On August 21, 2018 at 9: 25 AM, it was observed that the bacteriology testing personal was documenting the Microscan ID system quality control records. 2. The Microscan gram positive ID system quality control records showed that the laboratory did not perform the quality control procedures from January 2, 2017 to August 20, 2018. The laboratory did not check nor document for positive and negative reactivity of each substrate included in this identification system. 3. The Microscan gram negative ID system quality control records showed that the laboratory did not perform the quality control procedures from January 9, 2017 to August 20, 2018. The laboratory did not check nor document for positive and negative reactivity of each substrate included in this identification system. 4. The laboratory did not check the reactivity of each substrate of the the following microscan ID system lots in use: for gram negative lot 2019-01-29 and for gram positive lot 2019-01-08. The laboratory did not document when those lots were placed in routine use. 5. The testing personnel #2 confirmed on August 21, 2018 at 9: 25 AM, that she was going to document the Microscan ID system quality control

	records with the quality from January 2, 2017 to August 20, 2018. She stated that she performed the quality control procedures but not recorded. 6. The bacteriology testing records showed that the laboratory processed and reported the following patients microorganisms identification by the Microscan ID system: a. From January 21, 2017 to March 24, 2017: 37 gram negative microorganisms identifications and 5 gram positive microorganisms identification. b. From September 11, 2017 to November 29, 2017: 30 gram negative microorganisms identifications and 11 gram positive microorganisms identification. c. From May 23, 2018 to July 18, 2018: 30 gram negative microorganisms identifications and 14 gram positive microorganisms identification. d. From July 19, 2018 to August 20, 2018: 23 gram negative microorganisms identifications and 8 gram positive microorganisms identification. This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on Microscan susceptibility tests quality control records (from August 24, 2016 to August, 21 2018) review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation and interview with the testing personnel #2 on August 21, 2018 at 9:25 AM, it was determined that the laboratory failed check with appropriate control organism(s) each batch, lot number, shipment of reagents and each day of testing the Microscan susceptibility tests from July 31, 2017 to August 20, 2018. The findings include: 1. On August 21, 2018 at 9:25 AM, it was observed that the bacteriology testing personnel was documented the Microscan susceptibility tests quality control records. 2. The Microscan susceptibility tests for gram positive microorganisms quality control records showed that the laboratory did not perform the quality control procedures from July 31, 2018 to August 20, 2018. 3. The Microscan susceptibility tests for gram negative microorganisms quality control records showed that the laboratory did not perform the quality control procedures from August 1, 2017 to August 20, 2018. . 4. The laboratory did not check the antimicrobial susceptibility tests of the the following Microscan reagents lots in use: for gram negative microorganisms lot 2019-01-29 and for gram positive microorganisms lot 2019-01-08. The laboratory did not documented when those lots were placed in routine use. 5. The testing personnel # 2 confirmed on August 21, 2018 at 9:25 AM, that she was going to document the Microscan susceptibility tests quality control records with the quality from July 31, 2017 to August 20, 2018. She stated that she performed the quality control procedures but not recorded. 6. The bacteriology testing records showed that the laboratory processed and reported the following patients antimicrobial susceptibility tests by the Microscan system: a. From September 11, 2017 to November 29, 2017: 30 gram negative microorganisms antimicrobial susceptibility tests and 11 gram positive microorganisms antimicrobial susceptibility tests. b. From

	May 23, 2018 to July 18, 2018: 30 gram negative microorganisms antimicrobial susceptibility tests and 14 gram positive microorganisms antimicrobial susceptibility tests. c. From July 19, 2018 to August 20, 2018: 23 gram negative microorganisms antimicrobial susceptibility tests and 8 gram positive microorganisms antimicrobial susceptibility tests. This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records (years 2017 and 2018) review and technical supervisor interview on August 21, 2018 at 1:00 PM, it was determined that the laboratory failed to perform QA policies revision for effectiveness to prevent recurrence of problems in the analytic systems requirements for Bacteriology and General Immunology subspecialties. The findings include: 1. The laboratory failed to meet the analytic system requirements in the subspecialties of Bacteriology and General Immunology. Refer to D 5002 and D 5014. 2. This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called. 3. The laboratory failed to perform QA policies revision for effectiveness to prevent recurrence of problems in the analytic systems requirements for Bacteriology and General Immunology subspecialties
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), Antinuclear Antibody IgG by immunofluorescence manufacturer's instructions, Antinuclear Antibody IgG by immunofluorescence testing records (2018), laboratory information system (LIS), Quality Assessment (QA) records (years 2017 and 2018) review , interview with the testing personnel # 2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the laboratory director failed to fulfill his responsibilities to comply with the analytic system requirements for the subspecialty of Bacteriology and General Immunology and failed to comply with the quality assessment requirements for the analytic system. Refer to D 6093 (The laboratory director failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology and General Immunology). Refer to D 6094 (The

	laboratory director failed to perform the QA policies revisions for effectiveness to prevent recurrence of problems in the analytic systems requirements for Bacteriology and General Immunology subspecialties). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018) review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), Antinuclear Antibody IgG manufacturer's instructions, Antinuclear Antibody IgG testing records (2018), laboratory information system (LIS) , interview with the testing personnel #2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology and General Immunology. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology from January 2, 2017 to August 20, 2018. Refer to D 5002. 2. The laboratory failed to ensure compliance with analytic system requirements for general immunology Antinuclear Antibody (ANA) IgG test by immunofluorescence. Refer to D 5014. 3. The laboratory failed to follow manufacturer instructions for the processing and reporting 5 out of 5 pediatric population serum specimens from January 2, 2017 to August 20, 2018. Refer to D 5405. This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records (years 2017 and 2018) review and technical supervisor interview on August 21, 2018 at 1:00 PM, it was determined that the laboratory director failed to perform the QA policies revisions for effectiveness to prevent recurrence of problems in the analytic systems requirements for Bacteriology and General Immunology subspecialties. Refer to D 5793.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in

	accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), laboratory information system (LIS) , Antinuclear Antibody IgG by immunofluorescence manufacturer's instructions, Antinuclear Antibody IgG by Immunofluorescence testing records (2018), interview with the testing personnel #2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the laboratory technical supervisor failed to fulfill his responsibilities and duties to ensure compliance with the quality control requirements. Refer to D 6117 (The laboratory technical supervisor failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology from January 2, 2017 to August 20, 2018). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), Antinuclear Antibody IgG by immunofluorescence manufacturer's instructions, Antinuclear Antibody IgG testing records (2018), laboratory information system (LIS) , interview with the testing personnel # 2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the laboratory technical supervisor failed to ensure compliance with the analytic system requirements for the subspecialty of Bacteriology from January 2, 2017 to August 20, 2018. Refer to D5403 (The laboratory did not have a writing procedure manual for Antinuclear Antibody (ANA) IgG test processed by immunofluorescence kit since from January 30, 2018 to August 10, 2018). Refer to D 5405 (A) (The laboratory failed to follow manufacturer instructions for the processing and reporting 5 out of 5 pediatric population serum specimens from January 2, 2017 to August 20, 2018). Refer to D5405 (B) (The laboratory failed to follow the manufacturer's instructions when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit) Refer to D5411 (The laboratory failed to follow the manufacturer's instructions when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit). Refer to D 5471 (The laboratory did not check each batch, lot number and shipment of reagents of Microscan identification system for positive and negative reactivity of each substrate included in this identification system from January 2, 2017 to August 20, 2018). Refer to D 5507 (The laboratory failed check with appropriate control organism(s) each

	batch, lot number, shipment of reagents and each day of testing the Microscan susceptibility tests from July 31, 2017 to August 20, 2018). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), Antinuclear Antibody IgG by immunofluorescence manufacturer's instructions, Antinuclear Antibody IgG by immunofluorescence testing records (year 2018), laboratory information system (LIS) , interview with the testing personnel #2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the testing personnel failed to fulfill the testing personnel responsibilities. Refer to D 6177 (The testing personnel #2 and #4 did not follow the quality control procedures to ensure compliance with the analytic system requirements for the subspecialties of Bacteriology and General Immunology).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Microscan ID and susceptibility tests system quality control records (from August 24, 2016 to August, 21 2018), review, bacteriology testing records (from August 24, 2016 to August, 21 2018), direct observation, Immuno Card H. Pylori manufacturer's instructions, H. Pylori testing records (years 2017 and 2018), Antinuclear Antibody IgG manufacturer's instructions, Antinuclear Antibody IgG testing records (year 2018), laboratory information system (LIS) , interview with the testing personnel #2 and the technical supervisor on August 21, 2018 at 12:40 PM, it was determined that the testing personnel failed to follow quality control procedures to ensure compliance with the analytic system requirements for the subspecialties of Bacteriology and General Immunology. Refer to D 5405 (A) (The laboratory failed to follow manufacturer instructions for the processing and reporting 5 out of 5 pediatric population serum specimens from January 2, 2017 to August 20, 2018). Refer to D5405 (B) (The laboratory failed to follow the manufacturer's instructions when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit) Refer to D5411 (The laboratory failed to follow the manufacturer's instructions when perform the Antinuclear Antibody (ANA) IgG test by immunofluorescence kit). Refer to D 5471 (The laboratory did not check each batch, lot number and shipment of

	reagents of Microscan identification system for positive and negative reactivity of each substrate included in this identification system from January 2, 2017 to August 20, 2018). Refer to D 5507 (The laboratory failed check with appropriate control organism(s) each batch, lot number, shipment of reagents and each day of testing the Microscan susceptibility tests from July 31, 2017 to August 20, 2018). This deficiency was cited on survey performed on October 09, 2014. As a results an Immediate Jeopardy was called.